The European Molecular Biology Laboratory (EMBL) is supportive of the European Commission's efforts to establish the European Health Data Space. EMBL-EBI (Hinxton, UK site) maintains the world's most comprehensive range of freely available molecular data resources. Developed in collaboration with colleagues worldwide, our databases and tools help scientists share data efficiently, perform complex queries and analyse the results in different ways. Our work supports millions of researchers working in all areas of the life sciences, from biomedicine to biodiversity and agri-food research.

It is within this context that we encourage the EC to make sure that the objective 1 listed in the current roadmap is included in the future legislative proposal towards the creation of the EHDS.

We agree that the processing of health data in Member States is fragmented, leading to obstacles and limited access to researchers (GDPR has not led to systemic improvements). To address this, relying on existing European and International Research Infrastructures (RIs), that can share experience and help ensure that data standards and data interoperability are applied across the EU will be critical. We feel it would be beneficial for the future legislative proposal to recognise and build upon the key role played by RIs.

An initiative focusing on this issue is the European Genome-phenome Archive (EGA), which provides a service for the permanent archiving and distribution of personally identifiable genetic and phenotypic data resulting from biomedical research projects. Data at EGA is collected from individuals whose consent agreements authorise data release only for specific research use. In this context, the Federated EGA will be a distributed network of repositories (nodes) for sharing human -omics data and phenotypes. Federated EGA gathers metadata of -omics data collections stored in national or regional archives and makes them discoverable across the EGA network. The Global Alliance for Genomics and Health (GA4GH) will be one such nodes, aiming to enable responsible genomic data sharing for the benefit of human health. We encourage the EC and the signatory Member States to the "1+ Million Genomes" initiative to consider this approach as the project develops.

Electronic Health Record systems are in need of equivalent efforts and bodies to make them more interoperable and therefore accessible for research. The lack of pan-European standards in this area is, and has been, a barrier to research and EU-wide collaborations that could turn into preventive strategies, better treatment, and innovation on medical devices.

In the next decade, genomic medicine is likely to enable risk stratification for a variety of diseases (cancer and rare diseases) by integrating whole-genome information. EMBL has supported and enabled its member states to make substantial progress in designing, delivering, and operating genomic medicine services (e.g. strategic and technical support to the UK 100,000 Genomes Project, and the Danish Genomic Medicine service). EMBL aims to implement a bespoke Genomic Medicine Platform, which will develop data structures, and standards that promote: (1) the proactive sharing of technology from EMBL with member states, (2) the provision of key reference knowledge bases for interpreting genomes, and (3) the responsible secondary use of genomics data for research, with systems that respect national legal and cultural requirements.

Finally, pan-European and international initiatives such as the European Open Science Could (EOSC) or the COVID-19 research data platform play an important role as enablers of health and related research data, though their role is not recognised in the current roadmap. Thanks to these initiatives, considerable progress has already been made towards greater availability of research data, therefore we feel that any future potential legislation should build upon their important work, and ensure complementary is achieved.